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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|------------------------|
| 10/589,601 | 09/29/2006 | Mohammed Yasin | LUC-019 | 8651 |
| 7590 David Silverstein Andover-Ip-Law Suite 300 44 Park Street Andover, MA 01810 | | | EXAMINER PEPITONE, MICHAEL F | |
| | | | ART UNIT 1796 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/589,601 | Applicant(s) YASIN, MOHAMMED | |
| | Examiner MICHAEL PEPITONE | Art Unit 1796 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/30/07, 8/16/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-49 and 51-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 33-49 and 51-52: Claim 33 is indefinite because it is unclear if “at least two members selected from the group consisting of:” requires at least two members from groups (i)-(iii), or if at least two members from any one of the groups would meet the claim limitation. Accordingly dependent claims 34-49 and 51-52 are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-37, 41-44, 46-49, and 51-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Munro *et al.* (US 6,447,798).

Regarding claim 33: Munro *et al.* teaches a bioadhesive composition (1:14-16; 2:64-3:2) comprising 15-60 wt% of monomers (4:40-42); 10 to 50 wt% of plasticizers (6:28-41); and about

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24 wt% to about 37 wt% water {as calculated by examiner} (11:65-12:42); wherein the monomers include a ethylenically unsaturated first monomer having a sulfonic acid moiety (3:35-65), and a ethylenically unsaturated second monomer having carboxylic acid functionality (3:66-4:21), and the ratio of sulfonic acid to carboxylic acid is not less than 2:1 (4:54-61).

Regarding claim 34: Munro *et al.* teaches 2-acrylamido-2-methylpropanesulfonic acid, and salts thereof (4:22-25).

Regarding claim 35: Munro *et al.* teaches (meth)acrylic acid and salts thereof (4:25-27).

Regarding claim 36: Munro *et al.* teaches 15-60 wt% of monomers, preferably 20 to 50 wt% (4:40-42).

Regarding claim 37: Munro *et al.* teaches the ratio of sulfonic acid to carboxylic acid is not less than 2:1 (4:54-61).

Regarding claims 41-43: Munro *et al.* teaches 10 to 50 wt% of plasticizers [instant claim 41] (6:28-41), specifically glycerol [instant claims 42-43] (6:35).

Regarding claim 44: Munro *et al.* teaches polyethylene glycol diacrylate {diester of polyethylene glycol} (5:29-30).

Regarding claims 46-47: Munro *et al.* teaches and about 24 wt% to about 37 wt% water {as calculated by examiner} (11:65-12:42).

Regarding claims 48-49: Munro *et al.* teaches up to 10 wt% of cationic monomer, specifically (3-acrylamidopropyl)trimethyl ammonium chloride (6:18-27).

Regarding claims 51-52: Munro *et al.* teaches bioadhesive wound dressings {medical bandages} (1:14-16; 3:13-18).

Claims 50 is rejected under 35 U.S.C. 102(b) as being anticipated by Munro *et al.* (US 6,447,798).

Regarding claim 50: Munro *et al.* teaches a bioadhesive hydrogel composition (1:14-16; 2:64-3:2) comprising 15-60 wt% of monomers having a sulfonic acid moiety (3:35-65; 4:40-42); 10 to 50 wt% of plasticizers (6:28-41); and about 24 wt% to about 37 wt% water {as calculated by examiner} (11:65-12:42); and (3-acrylamidopropyl)trimethyl ammonium chloride (6:18-27) {corresponding to mixture A}.

Claims 33-34, 38-39, 41-43, 46-47 and 51-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Al-Lamee *et al.* (US 2003/0153964).

Regarding claim 33: Al-Lamee *et al.* teaches a bioadhesive composition (§ 1) comprising about 50 wt% of monomers {as calculated by examiner} (§ 17-34; 40; 57-58); 2 to 20 wt% of plasticizers (§ 41); and 5 to 60 wt% water (§ 40); wherein the monomers include an alkoxy polyethylene glycol (meth)acrylate (§ 17-28), and a ethylenically unsaturated second monomer having sulfonic acid moiety (§ 33-34).

Regarding claim 34: Al-Lamee *et al.* teaches 2-acrylamido-2-methylpropanesulfonic acid, and salts thereof (§ 33-34).

Regarding claim 38-39: Al-Lamee *et al.* teaches methoxy polyethylene glycol (meth)acrylate (§ 25-28), in an amount of about 6 wt% {as calculated by examiner (§ 65-66; 72)}.

Regarding claims 41-43: Al-Lamee *et al.* teaches 2 to 20 wt% of plasticizers [instant claim 41] (§ 41), specifically glycerol [instant claims 42-43] (§ 41).

Regarding claims 46-47: Al-Lamee *et al.* teaches 5 to 60 wt% water (§ 40).

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Regarding claims 51-52: Al-Lamee *et al.* teaches bioadhesive wound dressings {medical bandages} (§ 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Munro *et al.* (US 6,447,798) as applied to claim 33 above, and further in view of Marchant *et al.* (US 6,297,337).

Regarding claim 40: Munro *et al.* teaches basic claimed composition [as set forth above with respect to claim 33], wherein an acrylic acid or analogue thereof is used as the second monomer (2:25-30), in an amount of 1 to 50 wt% (4:62-67).

Munro *et al.* does not teach β -carboxyethyl acrylate as an acrylic acid analogue. However, Marchant *et al.* teaches a bioadhesive composition (1:1-7) comprising β -carboxyethyl acrylate [instant claim 40] (3:63-66). Munro *et al.* and Marchant *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of bioadhesive compositions. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined β -carboxyethyl acrylate, as taught by Marchant *et al.* in the invention of Munro *et al.*, and would have been motivated to do so since Marchant *et al.* suggests that β -

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carboxyethyl acrylate forms hydrogels (5:63-67), and is an equivalent alternative means of providing bioadhesive compositions.

Claims 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munro *et al.* (US 6,447,798) as applied to claim 33 above, and further in view of Munro *et al.* (US 2002/0015689).

Regarding claim 44-45: Munro *et al.* ('798) teaches the basic claimed composition [as set forth above with respect to claim 33] further comprising surfactants (9:10-16).

Munro *et al.* ('798) does not teach specific surfactants. However, Munro *et al.* ('689) teaches a bioadhesive composition (§ 2) comprising surfactants (§ 78-88), specifically polyoxoethylene stearyl ether [instant claims 44-45] (§ 79). Munro *et al.* ('798) and Munro *et al.* ('689) are analogous art because they are concerned with a similar technical difficulty, namely the preparation of bioadhesive compositions. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined the surfactant polyoxoethylene stearyl ether, as taught by Munro *et al.* ('689) in the invention of Munro *et al.* ('798), and would have been motivated to do so since Munro *et al.* ('689) suggests that such surfactants removes grease from the skin without reducing the work of adhesion of the coating (§ 89), and is an equivalent alternative means of providing bioadhesive compositions.

The prior art made of record and not relied upon is considered pertinent to applicants' disclosure. See attached form PTO-892.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PEPITONE whose telephone number is (571)270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo, Ph.D./
Supervisory Patent Examiner, Art Unit 1796
27-Sep-08

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23-September-08